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Fulbright & Jaworski L L P
600 Congress Avenue
Suite 2400
Austin, TX 78701

EXAMINER

MEHTA, ASHWIN D

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

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Paper No. 12182003

Application Number: 09/606,808
Filing Date: June 28, 2000
Appellant(s): LARKINS ET AL.

Robert Hanson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 14 October 2003.

- I. A statement identifying the real party in interest is contained in the brief.

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II. The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

III. The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 1, 4-6, and 18-21 are allowed. Claims 2, 3, 7-17, and 22-39 remain rejected and stand appealed.

IV. No amendment after final has been filed.

V. The summary of invention contained in the brief is correct.

VI. The Appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

Claims 2, 3, 7-17, 25-28, and 37-39 remain rejected under 35 U.S.C. 112, 2nd paragraph. The rejection is withdrawn from claims 18-24 and 29-36.

Claims 14-17 and 22-39 remain rejected under 35 U.S.C. 112, first paragraph, as not being supported by an adequate written description. The rejection is withdrawn from claims 2, 3, and 7, upon further consideration.

Claim 24 was also objected to in the Office action mailed 16 July 2003, as being in improper dependent form for failing to further limit the subject matter of a previous claim. Appellants did not address this objection.

VII. Grouping of the Claims

Appellant's brief includes a statement that claims 2, 3, and 7-39 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

VIII. The copy of the appealed claims contained in the Appendix to the brief is correct.

IX. Listing of the prior art.

5,523,520

Hunsperger et al.

06-1996

Eshed et al. "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato" Genetics, Vol. 143, (August 1996), pp. 1807-1817.

Kraft et al. "Linkage Disequilibrium and Fingerprinting in Sugar Beet" Theoretical and Applied Genetics, Vol. 101 (2000), pp. 323-326

X. Grounds of Rejection

Claims 2, 3, 7-17, 25-28, and 37-39 on appeal stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellants regards as the invention. The rejection is withdrawn from claims 18-24 and 29-36, upon further consideration of Appellants' arguments.

In claim 2: the recitation “further defined as an essentially homogenous population of inbred corn seed” renders the claim indefinite. It is unclear what affect this recitation has on the scope of the claim. Claim 1 reads, “Inbred corn seed of the corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192. Thus claim 1 is limited to seed of corn plant LIZL5. Claim 2 is directed to “The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.” The “further defined as” recitation in claim 2 renders the claim indefinite because it is unclear what affect this recitation has on the scope of the claim. Giving claim 2 its plain meaning, the inbred corn seed of claim 1 must, by definition, be a homogeneous population. Thus the “essentially homogeneous” language would appear to be superfluous. However, reading the claims in light of the specification, lines 17-22 on page 5 indicate that inbred seed can form less than 100% of an essentially homogeneous population. Thus the scope of claim 2 is unclear. Note that if claim 2 were amended to read, “An essentially homogeneous population of corn seeds consisting essentially of the inbred corn seed of claim 1”, the claim would have a definite meaning.

Appellants' Argument and Examiner's Response:

Appellants argue that claim 1 is directed to corn seed of the corn plant of LIZL5, and that claim 2 further narrows this by reciting a population of seed of claim 1. Appellants argue that this constitutes a further limitation of claim 1, as claim 1 does not require a population (Appeal Brief, page 5, 1st full paragraph).

However, as discussed in the rejection above, parent claim 1 is directed to a single variety of seed, that of the corn plant LIZL5, a sample of said seed having been deposited under ATCC

Accession No. PTA-2192. The scope of claim 2 is indefinite because it is not clear whether such claim encompasses non-LIZL5 members of the population.

Appellants continue, arguing that the term, “population” has a well known meaning in the art, and provide a definition for the term from the on-line version of the Merriam-Webster Dictionary, in Exhibit A (Appeal Brief, page 5, 2nd full paragraph). This definition does not indicate that all members of a population are genetically identical, and thus supports the Examiner’s position. The essentially homogeneous population of claim 2 can contain seeds that are not genetically identical to LIZL5, but parent claim 1 encompasses only seed that produces corn plant LIZL5. As noted above, amending claim 2 to read, “An essentially homogeneous population of corn seeds consisting essentially of the inbred corn seed of claim 1” would obviate the rejection.

In claim 3: the recitation “further defined as essentially free from hybrid seed” renders the claim indefinite, for reasons similar to the rejection of claim 2. The recitation “essentially free” indicates that claim 3 encompasses seed other than LIZL5. Further, claim 1 does not make any mention of hybrid seed. Amending claim 3 to read, “A population of corn seeds consisting essentially of the inbred corn seed of claim 1, and essentially free from hybrid seeds” would obviate the rejection.

Appellants’ Argument and Examiner’s Response:

Regarding the rejection of claim 3, Appellants again argue that the claim further defines the claim from which it depends by requiring that the seed be free of hybrid seed, and that this limitation is not found in the independent claim (Appeal Brief, paragraph bridging pages 5-6).

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However, first, claim 3 does not require the seed of claim 1 to be free of hybrid seed, but to be essentially free of hybrid seed. Because of the term, “essentially”, some hybrid seed can apparently be present in the subject matter encompassed by claim 2. Further, claim 1 only encompasses corn seed of the corn plant LIZL5. There are no hybrid seeds present in the subject matter of claim 1. The scope of claim 3 is indefinite because it is not clear whether such claim encompasses any hybrid seeds. As noted above, amending claim 3 to read, “A population of corn seeds consisting essentially of the inbred corn seed of claim 1, and essentially free from hybrid corn seeds” would obviate this rejection.

In claim 7: the recitation “An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5” in lines 1-2 renders the claim indefinite. LIZL5 seed can only produce LIZL5 plants. The claim does not mention any other type of seed. The population can therefore only consist of LIZL5 plants. It is then not clear why the population is referred to as “essentially homogeneous,” since such populations can comprise more than one variety of plant. Amending claim 7 to read, “An essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of inbred corn plant LIZL5, a sample of said inbred seed having been deposited under ATCC Accession No. PTA-2192” would obviate this rejection.

Appellants’ Argument and Examiner’s Response:

Appellants argue that a population need not be essentially homogeneous (Appeal Brief, page 6, 1st full paragraph). However, the claim clearly states, “An essentially homogeneous population of corn plants...”

Appellants provide the definition for “homogeneous” from the on-line version of the Merriam Webster Dictionary (Exhibit B), and argue that the relevant definition is “of uniform structure or composition throughout.” Appellants continue, arguing that a population of plants grown from the seed of corn variety LIZL5 need not be of uniform structure and composition, and that the plants may vary in several characteristics due to environmental or other conditions, but still constitute a population of corn plants produced by growing the seed of corn variety LIZL5 (Appeal Brief, page 6, 1st full paragraph).

However, the rejection never mentioned that the claim is indefinite because the individual LIZL5 plants of the population vary in size and shape, while possessing the identical genome. Rather, the rejection clearly raised the issue that an essentially homogeneous population of corn plants, which according to the specification can comprise multiple varieties of plants, cannot be produced by growing only one variety of seed. It is rather well known in the art that, when referring to plants, the term “variety” is used to distinguish genetically distinct taxonomic groups below the species level. LIZL5 is a variety of corn plant. Corn plant “X” is another variety of corn plant, and is genetically distinct from variety LIZL5. LIZL5 seed cannot produce “X” corn plants, but can only produce LIZL5 corn plants. It is not at all clear why Appellants are arguing that an “essentially homogenous population of corn plants” refers to the non-uniform nature of the same variety of corn plant, when the definition in the specification (page 5, lines 17-20) concerns the amounts of genetically different varieties of corn that can be in a population. Claim 7 indicates that growing only the seed of the inbred corn plant LIZL5 produces the corn plants of the essentially homogeneous population of corn plants. But if only one variety of seed is being grown, only one variety of corn plant can be produced. It therefore remains unclear why

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claim 7 is directed to an essentially homogeneous population of corn plants that, according to the specification, can comprise more than one variety of plant. If the population of claim 7 is to encompass only plants produced by growing LIZL5 seeds, as Appellants appear to be arguing, it is not clear why the claim is directed to an essentially homogeneous population of corn plants. The definition on page 5 also indicates that an essentially homogenous population of an inbred corn seed may be comprised of 100% of that seed. However, limitations of the specification cannot be read into the claims. As noted above, amending claim 7 to read, "An essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of inbred corn plant LIZL5, a sample of said inbred seed having been deposited under ATCC Accession No. PTA-2192" would obviate this rejection.

In claims 8, 10, and 13: the recitation "capable of expressing" in line 1 renders the claim indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation in claims 8 and 10 be replaced with --having--. In claim 13, it is suggested that the recitation "is capable of expressing" be replaced with --has--.

Appellants' Argument and Examiner's Response:

Appellants argue that the term "capable" is well known in the art and is thus fully definite, and that claim breadth is not indefinite. Appellants argue that one of skill in the art would understand whether a corn plant is capable of expressing all of the traits of corn plant LIZL5 by way of its biological deposit, and one would therefore ascertain whether a plant is

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capable of expressing all of the traits of LIZL5 based on direct comparisons (Appeal Brief, paragraph bridging pages 6-7).

However, it is maintained that the recitation, “capable of expressing”, renders the claim unclear because the recitation can be interpreted to indicate that, while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered “capable of expressing” that gene, and the trait associated with that gene, and is such a plant encompassed by the claims? Furthermore, traits such as plant height or yield are environmentally influenced. A particular value for plant height or seed yield observed in Appellant’s tested growing environment may not be observed in another environment. The Examiner, in the Office action mailed 16 July 2003, suggested replacing the recitation in claims 8, 10, and 13 with either --having-- or --has--. Such an amendment particularly points out that the claimed plant does have all of the morphological and physiological characteristics of LIZL5, while not requiring all of the characteristics to be expressed at all times of the plant’s life cycle.

In claim 9: the recitation “further comprising a cytoplasmic or nuclear gene conferring male sterility” renders the claim indefinite. The recitation appears to broaden the scope of its parent claim, or to raise some doubt as to whether the corn plant of claim 9 must be male sterile. The specification does not define plants expressing all the physiological and morphological

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characteristics of LIZL5 as being male sterile, or as comprising a cytoplasmic or nuclear gene that confers male sterility; in fact, the plant of claim 8 (from which claim 8 depends) is male fertile. Thus claim 9 cannot incorporate all the limitations of claim 8 because it is directed to a plant that is not male fertile. It is suggested that the claim be amended to recite that the plant was produced from the plant of claim 8 and to indicate how the cytoplasmic or nuclear gene conferring male sterility was introduced into the plant of claim 8.

Appellants' Argument and Examiner's Response:

Appellants argue that the claim is a proper dependent claim that specifies an additional characteristic, specifically, "a cytoplasmic or nuclear gene conferring male sterility", which is not in the independent claim. Appellants argue that claim 9 therefore contains a reference to the parent claim, contains a further limitation of the subject matter claimed in the main claim, and incorporates all elements of the claim from which it depends, and is therefore in proper dependent form pursuant to 37 CFR 1.75(c) (Appeal Brief, page 7, 1st full paragraph). Regarding the Examiner's suggestion, Appellants argue that a composition claim is a proper claim format and that there is no requirement that the claim be in product by process format. Appellants argue that the means by which the plant is made are irrelevant to the definiteness of the claims, as the claims meet all requirements for a proper dependent composition claim (Appeal Brief, page 7, 2nd full paragraph).

However, claim 9 does not incorporate all elements of the parent claim. The plant of parent claim 8 is capable of expressing all of the morphological and physiological traits of LIZL5, which is male fertile. The plant of claim 9, however, is not male fertile. Therefore, claim 9 does not incorporate all elements of the claim from which it depends. Further, as the

plant of claim 8 is male fertile, it is contradictory to say that claim 9 incorporates all elements of claim 8, yet is directed to a plant that is not male fertile. The following amendments are suggested: introduce a new claim 40 that reads, --A method of producing a male sterile corn plant comprising transforming the plant of claim 4 with a nucleic acid molecule that confers male sterility.--, and a new claim 41 that reads, --A male sterile corn plant produced by the method of claim 40.--

The rejection of claim 11, in regards to the recitation, “derived from”, is withdrawn, upon further consideration of Appellants’ arguments. However, note that claim 11 remains rejected because it depends from claim 10.

The rejection of claim 12, in regards to the recitation, “cells are in the form of protoplasts”, is withdrawn, upon further consideration of Appellants’ arguments. However, note that claim 12 remains rejected because it depends from claim 11.

In claims 14 and 17: the recitation, “in accordance with” renders the claim indefinite. It is not exactly clear what this recitation means, making the metes and bounds of the claim unclear.

Appellants’ Arguments and Examiner’s Response:

Appellants provide the definition for “accordance” that appears in the on-line version of the Merriam-Webster Dictionary, one of which is “agreement, conformity.” Appellants argue

that the term therefore has a well known meaning in the art and its use in the claim is not indefinite (Appeal Brief, page 8, 2nd full paragraph).

First, it is noted for clarification purposes that Table 6 in the specification actually shows SSR profiles, not RFLP genetic marker profiles as indicated in claims 14 and 17.

It remains unclear whether the claimed inbred plant cell or plant has the SSR profile or the genetic isozyme typing profile of Tables 6 and 7. It is not clear, for example, what is meant by an SSR profile that is in conformity with the profile shown in Table 6. Is the SSR profile the same, or is it not the same, as that shown in Table 6? Would an SSR profile that generally follows the trend of the profile of Table 6, but which differs at one or a few loci, be considered in "conformity" with the profile of Table 6? It is not clear what is meant by a marker profile that "agrees" with another marker profile. Are they the same or not? If the profiles are not exactly the same, then it is not clear what the differences are. If Appellants intend for the claimed inbred plant cell or plant to have the same profiles as those shown in Tables 6 and 7 for corn plant LIZL5, it is suggested that part (a) of claims 14 and 17 be replaced with --the SSR profile for corn plant LIZL5 shown in Table 6--, and that part (b) of the claims be replaced with --the genetic isozyme typing profile for corn plant LIZL5 shown in Table 7--.

The rejection of claim 19, for being improperly dependent on claim 18, is withdrawn, upon further consideration of Appellants' arguments.

In claim 25: the recitation “further comprising a single locus conversion” renders the claim indefinite. The recitation appears to broaden the scope of claim 4, or raises some doubt as to whether the plant has all of the traits expressed by the plant of parent 5.

Appellants’ Arguments and Examiner’s Response:

Appellants argue that the recited limitation is in addition to that of the main independent claim. Appellants argue that the single locus is added to and modifies the plant recited in the independent claim, that claim 25 contains a reference to the parent claim, contains a further limitation of the subject matter claimed in the main claim, and incorporates all elements of the claim from which it depends (Appeal Brief, page 9, 2nd full paragraph).

However, claim 25 adds an additional locus, and possibly an additional trait expressed by that locus, to the plant of claim 4. For example, the single locus may confer increased resistance against insects. The plant of claim 4 may be susceptible to insect damage, while the plant of claim 25, because of the additional locus, would be resistant to insects. Or the single locus may confer the trait of male sterility on the plant, whereas inbred corn plant LIZL5 is male fertile. It is unclear if the plant of claim 25 has all of the traits possessed by the plant of claim 4. Further, the definition for “single locus converted plants” in the specification (page 21) indicates that essentially all of the “desired” morphological and physiological traits of the inbred are recovered, in addition to the characteristic conferred by the single locus. All of the elements of the parent claim have not been incorporated into claim 25, if the plant of claim 25 only has the “desired,” as opposed to all, the traits of LIZL5.

In claim 26: the recitation “wherein the single locus was stably inserted into *a* corn genome” (emphasis added) renders the claim indefinite. It is not clear if the corn genome is that of LIZL5 or that of another corn plant.

Appellants’ Arguments and Examiner’s Response:

Appellants note that the single locus may or may not have been directly inserted into the genome of the claimed plant, but argue that this does not render the claim indefinite, because the single locus may have been inserted into a parent plant of variety LIZL5 and self pollinated to produce the claimed plant. Appellants argue that there is no need that the very plant claimed have been directly transformed because a single locus is stably transmitted through generations (Appeal Brief, paragraph bridging pages 9-10).

However, claim 25 makes no mention of any parent plant of inbred corn plant LIZL5. Further, a parent plant of inbred LIZL5 is itself LIZL5. Therefore it remains unclear, what other genomes are encompassed by “a corn genome”, and how does it relate to the plant of claim 26? Further, if the single locus is transformed into an entirely unrelated plant and introduced into LIZL5 by crossing and selection, the resultant plant would have the single locus but it would not otherwise be exactly the same as LIZL5.

In claim 28: the recitations, “yield enhancement,” “improved nutritional quality,” and “enhanced yield stability” are relative terms that have no definite meaning, making the metes and bounds of the claim unclear.

Appellants’ Arguments and Examiner’s Response:

Appellants argue that, while the terms are relative, they must be read in the context of the claim in which they are found. Appellants argue the subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability, and that it is understood that the enhancement of yield or yield stability and improvement in nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim would thus be fully understood by one of skill in the art (Appeal Brief, page 10, 2nd full paragraph).

However, what one may consider an enhancement or improvement over a plant lacking the single locus may not be considered so by another, in the absence of a defined standard that must be met. Further, what nutritional qualities are contemplated, and how are they improved?

The rejection of claims 29 and 30, for the recitation, “pre-selected DNA”, is withdrawn, upon further consideration of Appellants’ arguments.

The rejection of claim 31, for the recitation, “PEG mediated transformation of protoplasts”, is withdrawn, upon further consideration of Appellants’ arguments.

In claim 37: the recitation, “preparable,” renders the claim indefinite. Is the plant, or is the plant not, prepared by the process of claim 30?

Appellants’ Arguments and Examiner’s Response:

Appellants argue that the claim is in product by process format, and is defined by the process of claim 30. Appellants argue that the product by process format is accepted and is not indefinite (Appeal Brief, paragraph bridging pages 11-12).

However, claim 37 is not defined by the process of claim 30, because the term “preparable” leaves open the possibility that the claimed fertile transgenic corn plant can be prepared by any other means. For example, if the plant of claim 37 is not prepared by the process of claim 30, can it be prepared by contacting cells of genetically distinct corn plant variety “X” with a preselected DNA, identifying a transformed transgenic cell and regenerating a fertile transgenic plant from said transgenic cell? It is suggested that simply replacing the term “preparable” with the term, --prepared-- would overcome the rejection.

Claims 14-17 and 22-39 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is withdrawn from claims 2, 3, and 7 upon further consideration of Appellants’ arguments.

The claims are broadly drawn towards any hybrid corn seed produced by the process of crossing the inbred corn plant LIZL5 with any second, distinct, inbred corn plant, and any hybrid corn plant produced by growing said hybrid corn seed; or to an inbred corn plant cell having an

SSR genetic marker profile in accordance with the profile in Table 6 or an isozyme typing profile in accordance with the profile in Table 7; any inbred corn plant produced by growing seed of inbred corn plant LIZL5, wherein said plant further comprises any single locus conversion; or a method of preparing a transgenic corn cell comprising providing cells of plant LIZL5 and contacting said cells with any pre-selected DNA, or any fertile transgenic corn plant produced by regenerating a transgenic plant from a transgenic cell of LIZL5 produced by said method; or seed of said fertile transgenic plant, or a plant grown from said seed and which comprises said pre-selected DNA.

The specification describes numerous morphological and physiological characteristics, and provides the names of SSR markers and isozyme loci, of inbred corn plant LIZL5 (page 22, lines 2-6; Tables 1 and 2, pages 22-24; page 24, line 15 to page 25, line 18; Table 3, pages 25-27; Table 6, pages 58-60; Table 7, pages 60-61). The specification indicates that a deposit of 2500 seeds of LIZL5 has been made with the American Type Culture Collection, under the Accession No. PTA-2192, under the terms of the Budapest Treaty (amendment to page 27 of the specification, in the paper submitted 19 February 2002, pages 2-3). It is noted that all restrictions to the availability of the public to the deposited seed will be irrevocably removed upon the granting of a patent (Exhibit 1 of the papers submitted 19 February 2002). The specification also describes morphological traits, names of SSR markers and isozyme loci, of a single hybrid corn plant, designated "7026255," produced by crossing LIZL5 with an inbred corn plant designated "16SCQ2" (page 49, lines 18-24; Table 5, pages 54-55; Table 8, pages 61-63; Table 9, page 64). The specification also compares performance data for hybrid 7026255 with other corn plants (page 52, lines 1-3, Table 4, page 53).

A review of the full content of the specification indicates that seed of inbred corn plant LIZL5, and hybrid seed produced by crossing a LIZL5 plant with any other corn plant, are essential to the operation and function of the claimed invention. A search of seed of inbred corn plant LIZL5 indicates that it is novel and unobvious.

A review of the language of claims 22-24 indicates that the claims are drawn to a genus, i.e., any and all hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing inbred corn plant LIZL5 with any second, distinct inbred corn plant. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-LIZL5 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-LIZL5 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ.

The specification does not describe any hybrid corn seeds or plants other than the plant designated "7026255." There is no evidence on the record of a relationship between the structure of the complete genome of hybrid 7026255 and the complete genome of other hybrids. Hybrids produced by crossing LIZL5 with other, distinct inbred corn plants would, of course, produce plants that do not express the same traits as LIZL5, and hybrids produced by crossing LIZL5 with distinct inbred corn plants other than 16SCQ2 also would not express the same traits as 7026255. The descriptions of LIZL5 and 7026255 do not provide any information concerning the morphological and physiological characteristics of other plants. In view of these considerations, a person of skill in the art would not have viewed the teachings of the

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specification as sufficient to show that the Applicant was in possession of the claimed genus of hybrid seeds and plants produced therefrom.

The specification also indicates that Table 6 provides names of loci where the SSR markers supposedly reside, for three different corn plants, and a numerical value for each marker that represents numbers of base pairs (specification, page 57, lines 14-15 and 20-21). The specification indicates on page 57, lines 17-18, that the SSR analyses were conducted at Celera AgGen, and on page 60, line 3, that primers used in the analyses are also from Celera AgGen.

Claims 14-17 are drawn to an inbred corn plant, or a cell thereof, capable of expressing all the physiological and morphological characteristics of corn plants produced by growing seed of inbred corn plant LIZL5, said plant or cell thereof comprising an RFLP genetic marker profile in accordance with the profile shown in Table 6 (this table actually shows SSR genetic marker profiles), or a genetic isozyme typing profile in accordance with the profile shown in Table 7; or any corn seed or tissue culture comprising said cell.

However, while names and numbers of base pairs of loci of the SSR markers are provided, the actual nucleotide sequences that make up the markers are not provided. Names of loci alone do not describe the structures of the markers themselves. Without a description of the sequences of the markers, one cannot confirm their presence. Table 7 provides names of loci where isozyme markers reside, for three different corn plants, and a numerical value that represents the numbers of alleles at isozyme loci types. It is noted that 16 of the 18 isozyme markers of LIZL5 in Table 7 are also found in at least two other corn varieties, those of the other plants of Table 7. Hence, the markers in Table 7 are not adequate to distinguish the claimed hybrids from other corn plants, as other corn plants contain almost all of the same markers.

The specification also indicates that single locus converted plants are defined as plants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus). The specification contemplates numerous different single loci involved in expressing various traits (pages 29-32). The specification provides the origin and breeding history of a single exemplary single locus converted plant, in which the trait of cytoplasmic male sterility was introduced not into corn plant LIZL5, but into another corn inbred (pages 32-33).

Claims 25-28 are drawn towards LIZL5 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation. A review of claims 25-27 indicate that they encompass a genus of corn plants, each species of which can differ in the morphological and physiological traits that they can express, since they would comprise different single locus conversions. Claims 25-27 also do not place any limitation on the trait conferred or affected by the single locus conversion. However, the specification does not describe identified or isolated single loci for all corn plant traits. While the specification, on pages 29-32, recites traits that are contemplated to be introduced into LIZL5, single loci governing all of these traits have not been identified. For example, single loci that govern yield enhancement or enhanced yield stability, recited in claim 28, are not described. Claims 25-27 also broadly encompass single loci that have not been discovered or isolated. A

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single locus governing “industrial usage” (recited in the specification on page 29, line 7), for example, is not known in the art.

The specification discusses methods for corn plant transformation (pages 64-76). The specification also indicates that pre-selected DNA may comprise any desired DNA to be introduced into a cell, and recites several types of genes of interest (page 70, line 7 to page 71, line 4). All transgenes, or pre-selected DNAs, that can be introduced into LIZL5 do not share the same structures and functions, and each transgene would have a different effect on the LIZL5 plant.

Claims 37-39 are drawn towards any fertile transgenic corn plant, preparable by contacting cells of inbred corn plant LIZL5 with any pre-selected DNA, identifying at least a first transgenic cell, and regenerating a fertile transgenic plant therefrom; or a seed of said transgenic plant; or a plant grown from said seed. A review of claim 37 indicates that there is no limit as to the identity of the pre-selected DNA to be inserted into the LIZL5 cell. The pre-selected DNA of the plant of claim 37 can therefore express any trait, or no trait at all. The specification at page 70, lines 7-10 indicates that pre-selected DNA may comprise any desired DNA to be introduced into a cell. However, for similar reasons discussed above for single locus-controlled traits, the specification does not describe isolated pre-selected DNAs for all corn plant traits. The transgenic plants may be altered from LIZL5 in any manner. However, the specification does not describe single transgenes (or “pre-selected DNA”) that have the ability to alter all given corn plant traits. For example, single locus conversions or transgenes that govern yield enhancement or enhanced yield stability are not described. Further, the transgenes may encode a product having any function, and which could change the traits expressed by LIZL5 in

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any manner. That is, the claimed transgenic plant may not retain all the traits that are expressed by LIZL5. Transcription factors, for example, may affect more than one LIZL5 trait.

Descriptions of such transgenic plants transformed with a pre-selected DNA encoding a transcription factor, or any other DNA that may alter one or more LIZL5 traits, are not presented.

Further, claims 38 and 39 are drawn towards seed of the fertile transgenic corn plant of claim 37, and a plant grown from said seed. The seed of claim 38 can only be produced by crossing the plant of claim 37 with any other corn plant, including any plant that is not LIZL5. Claims 38 and 39 therefore also encompass hybrid progeny of the plant of claim 37. Such hybrid progeny are not described, for the reasons discussed above for claims 22-24.

Claims 29-36, drawn towards a method of preparing transgenic LIZL5 corn cells, are included in this rejection, as all of the materials required for the method (pre-selected DNAs) are not described. The claimed method is also not described since the products produced by it, encompassed by claims 37, are not described. Given the breadth of the claims encompassing all hybrid corn seeds produced by crossing LIZL5 to any other corn plant, and LIZL5 plants comprising any single locus conversion or any pre-selected DNA, and the description in the specification of only LIZL5 and a single hybrid, "7026255," produced therefrom, it is submitted that the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

Appellants' Arguments and Examiner's Response:

In the Appeal Brief submitted 14 October 2003, Appellants again argue that the hybrid seeds and plants of claims 22-24 are described because they have LIZL5 as a parent and therefore contain a copy of the same genome as corn plant LIZL5, and that they have inherited half of their genetic material from LIZL5 (Appeal Brief, page 13, 1st full paragraph).

First, the Examiner would like to address a statement made by Appellants that may be a point of confusion. Appellants state, "All of the claimed hybrid plants having LIZL5 as a parent will therefore contain a copy of the same genome as corn plant LIZL5" (emphasis added; Appeal Brief, page 13, 1st full paragraph). By stating that the hybrids contain the same genome as LIZL5, this statement can be interpreted to mean that the entire genome of any of the claimed hybrids is identical to the entire genome of LIZL5. Since inbred corn plant LIZL5 must be crossed with a different corn plant to produce the claimed hybrids, the claimed hybrids cannot have entirely the same genome as LIZL5. It appears to the Examiner that Appellants did not intend to indicate that all of the claimed hybrid plants have entirely the same genome as LIZL5, as Appellants then immediately state, "That is, because LIZL5 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant LIZL5..." (emphasis added), which correctly indicates that all hybrids would inherit one-half, not all, of their genome from LIZL5.

The Examiner maintains that the claimed hybrids will not have the same morphological and physiological characteristics as LIZL5. LIZL5 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of morphological and physiological characteristics that are different from each other, and which are

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also different from those expressed by LIZL5. That all hybrids will inherit half of their alleles from LIZL5 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of LIZL5 with any of the traits that it expresses. Further, the claimed hybrids will inherit one allele for every gene from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from LIZL5, or how the products of those alleles, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and on the epigenetic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from LIZL5 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.

For example, if LIZL5 carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the inheritance of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is clear that the mere provision of one-half of the hybrid's genetic complement being inherited from LIZL5 is woefully inadequate to describe the resultant hybrid, either genetically or morphologically.

Appellants also argue that the entire genetic contribution of corn plant LIZL5 is described by way of deposit of seed of LIZL5 with the ATCC, and believe that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishes them from other plants. In support of their argument, Appellants cite the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposit material (Appeal Brief, page 13, 1st full paragraph). However, in the patent considered in that decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed. As in *Enzo*, here the deposited inbred does not correspond exactly to the claimed hybrid. However, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited LIZL5 seed. The function of the plant grown from a LIZL5 seed is correlated with the structure of its entire genome, not just one half. The function of the claimed hybrid plants grown from the claimed hybrid seeds is correlated with the structures of their entire genomes, not just the alleles inherited from LIZL5. Further, half of the alleles of the hybrid are inherited from the other parent, and are not described by the deposited LIZL5 seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited LIZL5 seed, as discussed above.

Appellants continue, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Appellants argue that

here, all of the members of the claimed genus of hybrids having LIZL5 as one parent share the identical feature of having the genetic complement of LIZL5 (Appeal Brief, paragraph bridging pages 13-14). For the reasons explained above, the hybrids do not have the entire genetic complement of LIZL5, but only half that complement. In *Eli Lilly*, the members of the genus shared a common function. In the instant application, the specification does not describe the functions (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the functions of the hybrids with the structure of the genetic complement of LIZL5. Furthermore, the genetic complement of the other unknown parent has not been described, and hence Appellants have not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred LIZL5 with any and all other inbred or hybrid corn plants.

Appellants argue that the claimed F1 hybrid plants having LIZL5 as one parent will share the same genetic complement from LIZL5, and are readily identifiable by the genetic marker analysis in Tables 6 and 8. Appellants argue that hybrid corn plant 7026255 has the SSR genetic marker profile of LIZL5 and includes the genetic markers from the second parent plant, and that this will be true for any other hybrid plant having LIZL5 as one parent, save for “an occasional difference at a locus due to spontaneous genetic rearrangements” (Appeal Brief, page 14, 1st full paragraph). However, while all of the claimed hybrids will inherit the SSR marker profile of LIZL5, they will not inherit the same genetic markers from the other parent as did hybrid 7026255, because they will have different parents, having different markers. The SSR marker profiles of the other parents are not described. Further, the description of corn plant 7026255 does not describe the morphological and physiological traits of all other corn plants that can be

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produced by crossing LIZL5 to any other corn plant. One skilled in the art cannot identify the morphological and physiological characteristics of corn plant 7026255 that will be expressed by all other members of the genus, nor can one identify the characteristics that will be different.

Further, while hybrid 7026255 has inherited the SSR marker profile of LIZL5, the specification does not describe the traits that are correlated with these markers. The traits expressed by 7026255 are not solely due to the presence of the alleles associated with the SSR markers inherited from the LIZL5 genome, or the genetic contribution of LIZL5, as discussed above. Further, written descriptions of each of the SSR and isozyme markers are not provided. The markers represent specific nucleotide sequences. While the markers are named, this is not sufficient to describe the nucleotide sequences that they represent. Further, none of these markers have been linked to any expressed traits.

It is also noted that the specification does not describe the sequences of the primers that were used to produce this SSR profile. The specification indicates on page 57, lines 17-18, that the SSR analyses were conducted at Celera AgGen, and on page 60, line 3, that primers used in the analyses are also from Celera AgGen. However, without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant.

It is also noted that 16 of the 18 isozyme markers of LIZL5 in Table 7 are also found in at least two other corn varieties, those of the other plants of Table 7. Hence, the markers in Table 7 are not adequate to distinguish the claimed hybrids from other corn plants, as other corn plants contain almost all of the same markers.

Further note: claims 14 and 17 are included in this rejection because the SSR and isozyme markers mention in Tables 6 and 7 are not described for the reasons discussed above.

Appellants continue, arguing that the second plant that is used to make the claimed hybrids is irrelevant, as any second plant capable of reproduction may be used to make the hybrid. Appellants argue that the claims cannot be said to lack written description for the second genetic complement, particularly given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art. Appellants point to the more than 250 patents issued for corn varieties as support, and argue that any one of these corn plants could be used to produce an F1 hybrid plant having LIZL5 as one parent, and each of these would share the genetic complement of LIZL5 (Appeal Brief, paragraph bridging pages 14-15 and page 15, 1st full paragraph).

However, again, it is the interaction of the products of all of the alleles of the claimed hybrids, not just the products of the alleles inherited from LIZL5, which determine the traits of the claimed hybrids. Each parent contributes one set of chromosomes to the hybrid progeny, and each set of chromosomes comprise one allele for each gene at every locus in the genome, wherein alleles are alternate forms of the same gene that occur at a given locus. A phenotypic trait of the plant results from the expression of the two sets of alleles. The resulting phenotype of the plant depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with other gene products in the genome. Some alleles of the same gene are dominant to others. The interaction of nonallelic genes by epistasis also affects the phenotype, and quantitative traits are determined by the combined effects of multiple genes. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrid's morphological and physiological traits, one cannot correlate the alleles inherited from LIZL5 alone, with the phenotype of the hybrid progeny. Thus, the deposit of LIZL5 seeds and the recitation of some phenotypic characteristics of corn plant LIZL5 is not

sufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing LIZL5 with a second, distinct corn plant. Appellants would have one believe that only half of a genome is sufficient to describe a plant. Yet, if only half of the genome of LIZL5 was deposited, it would not have been enough to describe its full genome, as discussed above.

Appellants then return to the genetic marker data, alleging that the Action (presumed to be the Office action mailed 02 December 2002, page 4) attempts to downplay the significance of the genetic marker data in the specification, that no effort was made to show that any substantial number of marker loci actually are shared by other plants (Appeal Brief, page 15, 2nd full paragraph). However, the specification shows that at least two other inbred corn plants, 01IBH2 and MM402A, share many of the same SSR loci (see Table 6). Further, the specification does not explain why the SSR data of inbreds 01IBH2 and MM402A were chosen for comparison with that of LIZL5 in Table 6, how related these inbreds are to LIZL5, and hence how useful the SSR markers are for distinguishing different corn lines. Also, the specification does not mention anything concerning the traits expressed by the 01IBH2 and MM402A plants, and how similar those traits are to the combination of traits expressed by LIZL5. Further, is a comparison to only two inbreds sufficient to establish that the set of SSR and isozyme markers in Tables 6 and 7 can distinguish plants as having LIZL5 as a parent from those that do not? Given that 01IBH2 and MM402A share many of the SSR markers possessed by LIZL5, is the number of markers statistically significant to distinguish this genome from all other genomes? Even if the number of markers is sufficient, the specification fails to correlate any function, or trait, expressed by LIZL5, or the claimed hybrids, with any of the markers.

Appellants argue, regarding the availability of genetic markers or the primers used to detect the markers, that the service used to detect SSR markers is commercially available to the public, that SSR and other genetic marker systems that are well known may potentially be used, as described in the specification on pages 56-57 (Appeal Brief, paragraph bridging pages 15-16). However, that the service used to detect SSR markers is currently commercially available is not a guarantee that it will remain so for the life of a patent issuing from the application. Further, the specification at pages 56-57 only provides a general discussion of other types of genetic markers, and does not describe any actual markers possessed by corn plant LIZL5.

Appellants next argue, in response to the Examiner's previous arguments that the morphological and physiological characteristics of the hybrids have not been described, and that the manner in which the genes inherited by the hybrids would be expressed or interact has not been shown, that the Examiner's position misses the point that Appellants have gone one step further by describing the claimed hybrid plants at the genetic level. Appellants assert that a better description could not be made than at the genetic level (Appeal Brief, page 16, 1st full paragraph). However, again, Appellants are attempting to describe the claimed hybrids by only half of their genome. Appellants have deposited LIZL5 seed and, by extension, the LIZL5 genome, since the cells of the LIZL5 seed contain the LIZL5 genome. The claimed hybrids inherit only half of this genome, and the claimed hybrids do not have all of the same functions as those possessed by LIZL5. Given the genetic composition at each locus of the second inbred chosen as the hybrid's parent, the resultant hybrid may even have fewer than one-half of the traits exhibited by LIZL5.

The specification also provides the locus of many SSR and isozyme markers in the genome of LIZL5. However, as discussed above, the specification does not correlate any function of the claimed hybrids with this genetic information. The specification does not correlate any traits with any genes or molecular markers of LIZL5, and therefore the claimed hybrids. Further, while LIZL5 seed has been deposited, none of the hybrid seeds, which produce plants having traits and functions that are different from LIZL5, have been deposited.

Appellants continue, arguing that the law makes no distinctions regarding the manner in which applicants choose to describe claimed compositions (Appeal Brief, paragraph bridging pages 16-17). However, the Examiner has not limited Appellants to describing the claimed composition in any specific manner. Appellants argue that they have described the genetic complement of parent plant LIZL5 that will be comprised in the claimed hybrid plants by way of the SSR and isozyme genetic marker profiles in Tables 5-8 (It is assumed Appellants meant Tables 6-8, as Table 5 actually presents morphological traits expressed by the one exemplified hybrid plant, 7026255). However, as discussed above, while loci where these markers are located are identified, the sequences of the markers, or of primers used to locate them, are not described, nor are any functions of any alleles that may be associated with the markers described.

Appellants repeat their argument that a further description of the claimed hybrid plants is provided in the specification by way of hybrid 7026255, and believe that this plant is representative of hybrids produced using LIZL5 as one parent, each of which comprise the genetic complement of the parent corn plant (Appeal Brief, page 17, 1st full paragraph). Appellants argue that Table 4 provides performance comparisons with other hybrid varieties

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(which do not have LIZL5 as a parent), that Table 5 presents morphological traits of 7026255 plants, and that Table 8 provides its SSR profile. Appellants argue that this information combined with the descriptions of LIZL5 and the shared structure among the hybrids is more than adequate to describe the claimed subject matter (Appeal Brief, page 17, 1st full paragraph). However, again, hybrids that do not share both of the same parents will not have the same traits. The performance comparisons of Table 4 and the morphological traits in Table 5 cannot be extended to any other hybrid plant that does not have both of the same parents as 7026255, and are not representative of all hybrids produced using LIZL5 as one parent.

Regarding claims drawn towards corn plant LIZL5 containing single locus conversions: Appellants appear to be arguing that the specification describes such plants, simply because the definition of “single locus converted plants” provided in the specification indicates that such plants possess essentially all of the desired morphological and physiological characteristics of plant LIZL5 in addition to the characteristics conferred by the single locus transferred. Appellants argue that because the specification indicates that the claimed plants possess “essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]”, that they have more than adequately described such plants (Appeal Brief, paragraph bridging pages 17-18). However, the specification does not describe any and all single locus conversion traits, nor the source of all of said traits. The traits conferred by the single locus may also change one or more of the traits expressed by LIZL5, depending on what the locus encodes. See the discussion of male sterility above, for example. Further, the descriptions of plants that express “essentially” all of the “desired” characteristics of LIZL5 are

not described. The definition indicates that the plants possess the “desired” characteristics of LIZL5. The “desired,” as opposed to the “undesired,” traits are not described.

Appellants cite *In re Gosteli* for indicating that the written description requirement does not require an applicant to describe exactly the subject matter claimed, but that the description must clearly allow persons of ordinary skill in the art to recognize what is claimed (Appeal Brief, paragraph bridging pages 17-18). However, the specification does not describe the traits expressed by all of the claimed plants, nor what set of traits are present in all of the claimed plants to allow persons of ordinary skill in the art to recognize the claimed plants. The claimed genus reads on a multitude of LIZL5 plants further comprising an additional single locus, and having a multitude of different morphological and/or physiological traits. As discussed, the specification does not describe plants that express only some or “desired” traits that are expressed by LIZL5, or how to distinguish such plants from LIZL5. Further, single loci, for example those encoding a transcription factor, may affect one or more traits expressed by LIZL5. The claimed plant then may not express all of the “desired” traits of LIZL5. Such plants are not described by the specification.

In response to the issue raised in the previous Office actions that the claimed plants encompass introducing genes, or single loci, that have yet to be discovered, Appellants argue that undiscovered genes are not claimed, and that the fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant, because it is the single locus conversion of corn plant LIZL5 that is claimed (Appeal Brief, paragraph bridging pages 18-19). However, if a gene has not been discovered or isolated at the time the instant application was filed, Appellants cannot be in possession of a corn plant into which this gene was deliberately

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introduced. Furthermore, at least claim 28 explicitly recites undiscovered genes, since single genes that alone govern “yield enhancement” or “enhanced yield stability” have not been discovered.

Appellants continue, arguing that under the Examiner’s reasoning, any claim could be read to encompass subject matter yet to be invented and therefore not described. For example, a corn plant transformed with a *Bacillus thuringiensis* gene (presumably encoding the insecticidal endotoxin) would be invalid because it would encompass corn varieties yet to be discovered (Appeal Brief, paragraph bridging pages 18-19). In this example, however, there is only one genetic structure that is relevant, that of the *B. thuringiensis* gene, and only one function, that of the insecticidal properties conferred by the product of the gene. A claim drawn towards a corn plant containing the gene may be described, if the structure and function of the gene is described. The corn plant comprising that gene has increased resistance against insects. In the instant application, the invention encompasses corn seed LIZL5 and the plant produced by it. The deposit of the seed satisfies the written description requirement for the LIZL5 seed, and the functions of the plant are described in Tables 1-3. Another locus that is introduced into LIZL5 would amend its structure and functions.

Appellants argue that the Examiner supposedly ignored evidence submitted in a prior response that the specification recites numerous single locus traits with a publication reference or patent number. Appellants go on to provide several examples (Appeal Brief, page 19, 1st full paragraph to page 21, 1st full paragraph). However, this argument was rebutted on page 5 of the Office action mailed 02 December 2002. While the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that certain genes

have been discovered or isolated. For example, the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability. If such single loci have not been discovered or isolated, Appellants cannot be in possession of LIZL5 plants comprising this single locus conversion. The claims broadly encompasses plant LIZL5 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Appellants cannot be in possession of plants further comprising single loci that have yet to be identified. It is also noted that the Examiner is not asking Appellants to identify each and every gene known to man by name, but to identify the types of single loci, that alone control a trait, that have been identified. For example, many genes or single loci were known in the prior art that confer disease resistance, or herbicide resistance. In the Office action mailed 02 December 2002, on page 5, it was suggested that the claims be amended to recite the types of single gene loci, not individual or specific loci names.

Appellants argue that techniques for introducing single locus traits by genetic transformation were well known (Appeal Brief, paragraph bridging pages 21-22). That methods to produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not describe the product itself.

Regarding claims drawn towards transgenic LIZL5 plants, Appellants argue that Section XII of the specification describes the creation of transgenic plants and cells of LIZL5 using microparticle bombardment or Agrobacterium (Appeal Brief, page 22, 2nd full paragraph). Section XII does teach the method steps performed to produce transformed tissue and plants, but does not describe the transgene that was introduced. The structure of the transgene, i.e., its DNA sequence, was not described. The phenotypic effect of the transgene in the transgenic plant

produced is likewise not described. Even if the example did reveal the transgene, the transgenic plant produced would not describe all other transgenic LIZL5 plants transformed with all transgenes.

Proposed claim amendments that address the subject matter of instant claims 25-37, which were previously discussed with Appellants but not accepted, are presented in Appendix A, at the end of this Examiner's Answer. A discussion of why these proposed claims are deemed acceptable is also provided below.

Claims 25-39 on appeal stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of transforming LIZL5 when the transgene is known in the art and whose effect when expressed in transformed plants is known, does not reasonably provide enablement for the methods of transforming LIZL5 with all transgenes, or for producing LIZL5 plants comprising single locus conversions by backcrossing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to inbred corn plant LIZL5 further comprising a single locus conversion; or to any method of preparing transgenic LIZL5 cells comprising contacting cells of inbred corn plant LIZL5 with any pre-selected DNA, having any function; or wherein said method further comprises regenerating a fertile transgenic plant; or a fertile transgenic plant produced by said method; or seed of said transgenic plant; or a plant grown from said seed.

The specification indicates that single locus converted plants are produced by crossing a first inbred of interest with another "donor" inbred parent plant, which contains the single locus that is to be introduced into the first inbred. The progeny of that cross is then backcrossed with the first inbred. The progeny of the backcross gets backcrossed with the first inbred several more times, until a plant is recovered that has essentially all of the desired morphological and physiological traits of the original, first inbred in addition to the trait (single locus) transferred from the donor inbred parent (specification, paragraph bridging pages 27-28). The specification provides the origin and breeding history of a single locus converted plant, in which the trait of cytoplasmic male sterility was introduced not into LIZL5, but rather into an inbred designated, "85DGD1," which is a proprietary inbred of DEKALB Genetics Corporation (pages 32-33).

A review of claim 25 indicates that it encompasses corn plant LIZL5, and therefore all of its morphological and physiological traits, and further comprising any single locus. The practice of crossing two plant varieties, each expressing two different desired traits for example, to obtain a single variety that expresses both desired traits is well-established. However, the specification does not teach any LIZL5 plants comprising a single locus conversion produced by backcrossing, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the single trait conferred by the introduced single locus. It is not clear that single loci may be introduced into the genetic background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in

one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single locus conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single locus conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art, in order to yield the claimed plants which differ from LIZL5 only in comprising a single locus conversion and by the expression of a single trait.

The specification also teaches that single loci may be introduced into LIZL5 plants by transformation (page 29, lines 4-5; page 30, line 23 to page 31, line 30). The specification indicates that methods for genetic transformation of corn are known in the art, and indicates that pre-selected DNA to be introduced into LIZL5 may comprise any gene of interest (paragraph

bridging pages 30-31; page 64, line 7 to page 68, line 14; page 70, line 7 to page 71, line 4). The specification teaches the introduction of two plasmids, termed "pMON30460", which contains an antibiotic-resistance gene (Fig. 1), and "pDPG915", which contains an unidentified, non-selectable gene of interest, into LIZL5 tissue by microprojectile bombardment, and regeneration of transgenic plants therefrom (page 68, line 16 to page 73, line 20). The specification also teaches the transformation of LIZL5 via *Agrobacterium*, in which the transformation plasmids contained antibiotic-resistant selectable markers (page 73, line 23, to page 76, line 6).

The method of claims 29-36 do not place any limits on the pre-selected DNA that can be introduced into LIZL5 cells, and the products of claims 37-39 may contain any pre-selected DNA. However, the specification does not enable transforming LIZL5 cells with all transgenes (pre-selected DNA). As broadly interpreted, the claimed plants and method encompass introducing any type of transgene into LIZL5, including those that have not been isolated at the time the application was filed. The prior art shows that hundreds of nucleotide sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed. One skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell. However, the claims do not place any limit on the pre-selected DNA to be introduced, and encompass transgenes for plant traits that have yet to be isolated. For example, isolated genes whose products confer yield enhancement are not known in the prior art. One skilled in the art cannot practice the claimed method and produce the claimed plants if nucleotide sequences whose product confer a desired trait has not been isolated at the time the instant invention was made. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at

1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by “its physical or chemical properties” (e.g. a DNA sequence). Also, the pre-selected DNA, as broadly interpreted, includes isolated genes whose functions are not known. If the effect of expressing a transgene in LIZL5 were not known, one skilled in the art would not know how to use the transformed plant. The specification, at page 70, for example, makes numerous suggestions as to what the pre-selected DNA may encode. However, the pre-selected DNA is not limited to these suggestions. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Further, the effects of transgene expression on the traits expressed by untransformed LIZL5 are unknown. The specification does not teach one how to use a transformed LIZL5 plant if all of the morphological and physiological traits of LIZL5 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Appellants’ Response:

Addressing the issue that the specification does not teach one skilled in the art how to use the claimed transgenic plants when the transgenes aren’t identified, Appellants first note that the introduction of DNA into a cell occurs without regard to the nucleic acid transformed, and that claims 25-39 require only a preselected DNA (Appeal Brief, page 23, 2nd full paragraph). However, the Examiner never doubted that the introduction of DNA into a cell occurs without

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regard to the nucleic acid transformed, or that methods to transform corn were known in the prior art.

Appellants argue that they need not disclose every transgene ever known or that could ever be isolated (Appeal Brief, paragraph bridging pages 23-24). However, again, the Examiner never required that the claims recite every transgene ever known. Rather, the issue raised was that one cannot make a transgenic plant with types of transgenes that have not been isolated, such as those that confer yield enhancement or enhanced yield stability. To make the distinction, an amendment is again suggested in which types of transgenes, not any specific transgene by name, contemplated by the specification, be inserted into parent claim 29. For example, many herbicide resistance genes or plant virus resistance genes were known in the prior art. The claims need not identify each and every such gene by name, but may simply indicate that the transgene may be an herbicide resistance gene or a plant virus resistance gene. If the gene is taught and known in the prior art, one skilled in the art would know how to make and use the claimed transgenic plant.

Turning to the aspect of the rejection concerning the enablement of corn plants of variety LIZL5 comprising a single locus conversion, Appellants argue that, as noted before, no basis has been given to show that these references have any relevance to corn plants. Appellants argue that there is no support for the Examiner's assertion that the cited references concerning petunias, sugar beets, and tomatoes would apply to corn, and that the Action attempts to require Appellants to show why this is not true. Appellants argue that it is the burden of the Office to support its rejections (Appeal Brief, page 24, 1st full paragraph, the paragraph bridging pages 24-25, and page 25, 1st full paragraph).

First, regarding Appellants' comment that their argument was presented before: it is noted that this rejection was first applied in the last Office action that was issued (mailed 16 July 2003), and Appellants could not have previously presented this argument. Further, the rejection was supported with cited references. The rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome. Linkage drag appears to be a phenomenon that occurs in all plant types. Examples are lacking in the prior art of plants in which linkage drag does not occur. There is no evidence that corn is exempt from this universal trend. Linkage drag, for reasons embellished in the previous Office action and repeated above, would prevent one skilled in the art from making the LIZL5 plants comprising single locus conversions as currently claimed.

Further, the single locus may encode any product having any function, and can therefore affect the other traits expressed by LIZL5. For example, if the single locus encodes a transcription factor, the expression of numerous genes may be affected, which in turn would affect the traits expressed by LIZL5. In such a scenario, one may not obtain a plant having all or even most of the desired morphological and physiological traits of LIZL5, in addition to the trait conferred by the single locus.

In order to produce a single locus converted plant, a first inbred of interest is crossed with another "donor" inbred parent plant, which contains the trait that is to be introduced into the first inbred. The progeny of that cross is then backcrossed with the first inbred. The progeny of the backcross gets backcrossed with the first inbred several more times, until a plant is recovered that has essentially all of the desired morphological and physiological traits of the original, first inbred in addition to the trait (single locus) transferred from the donor inbred parent

(specification, paragraph bridging pages 27-28). The claims, however, do not mention the method of producing LIZL5 plants comprising a single locus conversion, but rather directly claim such plants. The claims broadly encompass plants that comprise exactly the genome of LIZL5, further comprising just a single additional locus. While the introduction of a desired trait from one plant into another using crossing techniques is well known in the prior art, what is not clear is that a plant that has exactly the same genome as LIZL5 is recovered, in addition to the introduced single locus. The claims encompass such plants. The very first cross involves crossing LIZL5 to another plant, resulting in a plant that expresses traits that are very different from those expressed by LIZL5, due to the presence of the genetic material from the non-LIZL5 plant. It is not clear, despite repeated backcrossing with LIZL5, that a plant having the exact same genome of LIZL5 is recovered (in addition to the introduced single locus), particularly in view of the genetic linkage of multiple genes conferring multiple additional traits, as established by the cited references. The specification attempts to address this by indicating that “essentially” all of the “desired” morphological and physiological traits of an inbred are recovered, in addition to the transferred single locus (paragraph bridging pages 27-28). However, the claims are directed to exactly plant LIZL5 further comprising the single locus.

Finally, Appellants return to the aspect of the rejection concerning transgenic plants, arguing that the claimed method of preparing a transgenic corn cell involving transformation of LIZL5 is described in the working examples in Section XII of the specification, and that plant transformation in general was very well known to those of skill in the art at the time the application was filed (Appeal Brief, page 25, 2nd full paragraph and the paragraph bridging pages

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25-26). However, as the use of the end product of the method is not taught, for the reasons discussed above, the method to make the product is also not taught.

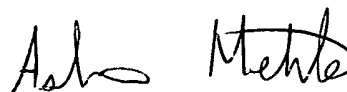
The Examiner would also like to note that, prior to the submission of the Appeal Brief of 14 October 2003 by Appellants, Supervisory Patent Examiner Amy Nelson faxed to Appellants a proposed, generic set of claim amendments that, after being rewritten to be particularly drawn towards the instant invention, would place the application in condition for allowance. The proposed claims particularly address the subject matter of, and would replace, pending claims 9 and 25-37, which are drawn towards LIZL5 plants further comprising a nuclear or cytoplasmic gene conferring male sterility, or LIZL5 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation, or a method of preparing a transgenic LIZL5 cell, or regenerating a transgenic plant therefrom. However, a response to the offer was never received from the Appellants for this application. The proposed amendments, as they would apply to the instant application, are provided here in Appendix A. Regarding the proposed claims 40-49, directed towards methods comprising transforming corn plant LIZL5: the method is considered acceptable to the Examiner because it indicates the traits that would be affected by the transgene, or it recites the type of transgene that is intended to be introduced into the plant. Of course, Appellants would not be limited to only those traits mentioned in the proposed claims. Any such trait may be recited, provided that there is written descriptive support in the specification and the prior art teaches that genes that affect such traits

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have been isolated. It is again noted that the Examiner is not requiring that the claims recite the actual names of any genes. Regarding the proposed claims 50-54, drawn towards a method of introducing a desired trait into the inbred plant of the invention using backcrossing techniques (which would result in plants comprising a single locus conversion, to use the terminology of the instant application): the proposed method claims are considered acceptable because they 1) indicate the type of traits that are contemplated, and 2) indicate that, after the deposited, inbred plant of the invention is crossed with a plant that contains the desired trait to be transferred, the progeny plant is to be backcrossed and selected at least four times, to ensure that undesirable genetic material from the donor plant is lost and that the resultant plant will also recover all of the traits of the original plant that are taught in Table 3 of the specification. It is important that the resultant plant retain the traits recited in Table 3, as it is this combination of traits that make inbred corn plant LIZL5 free of the prior art and described. Note that the proposed method claim does not require the recovery of LIZL5 traits that are absent from Table 3. The method of the proposed claim results in a plant having the traits of LIZL5 recited in Table 3, and the introduced trait.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Ashwin D. Mehta
Primary Examiner
Art Unit 1638

January 20, 2004

Conferees



Bruce Campell
Supervisory Patent Examiner
Art Unit 1661



Amy Nelson
Supervisory Patent Examiner
Art Unit 1638

Fulbright & Jaworski LLP
600 Congress Avenue
Suite 2400
Austin, TX 78701

Appendix A- Proposed New Claims

40. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 4 with a nucleic acid molecule that confers male sterility.
41. A male sterile corn plant produced by the method of claim 40.
42. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 4 with a transgene that confers herbicide resistance.
43. An herbicide resistant corn plant produced by the method of claim 42.
44. The corn plant of claim 43, wherein the transgene confers resistance to an herbicide selected from the group consisting of glyphosate, sulfonylurea, and phosphinothricin.
45. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 4 with a transgene that confers insect resistance.
46. An insect resistant corn plant produced by the method of claim 45.
47. The corn plant of claim 46, wherein the transgene encodes a *Bacillus thuringiensis* Bt toxin.

48. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 4 with a transgene that confers disease resistance.
49. A disease resistant corn plant produced by the method of claim 48.
50. A method of introducing a desired trait into inbred corn line LIZL5 comprising:
- (a) crossing LIZL5 plants grown from LIZL5 seed, representative seed of which has been deposited under ATCC Accession No. PTA-2192, with plants of another corn line that comprise a desired trait to produce F1 progeny plants, wherein the desired trait is selected from the group consisting of male sterility, herbicide resistance, insect resistance, and disease resistance;
 - (b) selecting F1 progeny plants that have the desired trait to produce selected F1 progeny plants;
 - (c) crossing the selected progeny plants with the LIZL5 plants to produce backcross progeny plants;
 - (d) selecting for backcross progeny plants that have the desired trait and traits of corn inbred line LIZL5 listed in Table 3 to produce selected backcross progeny plants; and
 - (e) repeating steps (c) and (d) three or more times in succession to produce selected fourth or higher backcross progeny plants that comprise the desired trait and all of the traits of corn inbred line LIZL5 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

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51. A plant produced by the method of claim 50, wherein the plant has the desired trait and all of the traits of corn inbred line LIZL5 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.
52. The plant of claim 51 wherein the desired trait is herbicide resistance and the resistance is conferred to an herbicide selected from the group consisting of: sulfonylurea, glyphosate, and phosphinothricin.
53. The plant of claim 51 wherein the desired trait is insect resistance and the insect resistance is conferred by a transgene encoding a *Bacillus thuringiensis* Bt toxin.
54. The plant of claim 51 wherein the desired trait is male sterility and the trait is conferred by a nucleic acid that confers male sterility.